K000554

MAR 1 4 2000

AXIS-II

Ultrasonic Ophthalmic Biometer

.510(k) Summary

(1) Submitter information

Name : Quantel Medical S.A.

Address: 89, Boulevard Etienne Clémentel
63100 Clermont-Ferrand - France -

Telephone: (+ 33) 473 25 62 27

Contact person: Dr. George MYERS (Official Correspondent).

Medsys Inc.
377 Route 17 South
Hasbrouck Heights, New Jersey 07064
Tel : 201-727-1703
Fax: 201-727-1708

Date prepared : January 2000

(2) Name of Device

Trade Name: "AXIS-II" Ultrasonic Biometer
Common Name: Biometer
Classification name: System, Imaging, Ultrasonic, Ophthalmic, 980IYO

(3) Legally-marketed predicate device

"B-SCAN" Ophthalmic Ultrasound Imaging System
510(k) number : K 926251
Decision date : Sept. 14th 1993

(4) Description

The AXIS-II is a small compact device Ultrasonic Biometer that uses the principles of sonar (pulsed ultrasound) to measure the axial length of the eyes. The device includes six popular formulas to calculate the implanted IOL power, using the Ultrasound Axial Length measurement.
The results may be printed through a parallel port PC computer printers.

AXIS-II

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510(k) Summary

(5) Intended Use

The Quantel Medical AXIS-II Ultrasonic Biometer is intended to be used for :
- the Axial Length measurement of the eye by ultrasonic means
- the implanted IOL power calculation, using the Axial Length measurement.

This IOL implantation is indicated for most types of cataract surgery.

(6) Performance Data

(a) Non-Clinical tests

The AXIS-II has passed all tests in relation with the following standards :
- IEC 601-1 for Electrical Security
- IEC 601-1-2 for Electromagnetic Compatibility

(b) Clinical tests

Since the AXIS-II uses the same technology as existing devices, clinical tests are not required.

(7) Conclusion

The AXIS-II Biometer is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2000

Quantel Medical, S.A.
C/O George H. Myers, Sc.D.
Official Agent
MedSys Inc.,
377 Route 17 South
Hasbrouck Height, NJ 07604

Re: K000554
Axis-II Ultrasonic Ophthalmic Biometer
Regulatory class: II
21 CFR 892.1560/Procode: 90 IYO
Dated: January 31, 2000
Received: February 18, 2000

Dear Dr. Myers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Axis-II Ultrasonic Ophthalmic Biometer, as described in your premarket notification:

Transducer Model Number

TP-01-b

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Diagnostic Ultrasound Indications for Use Form

Page: 1 of 1

510(k) Number (if known):

Device Name: **Quantel Medical "AXIS-II" Biometer**

Intended Use: The Quantel Medical AXIS-II Ultrasonic Biometer is intended to be used for :
- the Axial Length measurement of the eye by ultrasonic means
- the implanted IOL power calculation, using the Axial Length measurement.

This IOL implantation is indicated for most types of cataract surgery.

Mode of operation

CLINICAL APPLICATION	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velovity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	N									
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Intra-luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)*										

Additional Comments:

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000554

Diagnostic Ultrasound Indications for Use Form

Page: 1 of 1

510(k) Number (if known):

Device Name: **Quantel Medical Transducer for Biometry (Ref : TP-O1-b)**

Intended Use: The Transducer for Biometry is intended to be used with the Quantel Medical AXIS-II Ultrasonic Biometer for the Axial Length measurement of the eye by ultrasonic means. This measurement is required to make the IOL calculation for most types of cataract surgery.

Mode of operation

CLINICAL APPLICATION	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velovity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic	N									
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Intra-luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal										
Other (Specify)*										

Additional Comments:

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000554